



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,567	06/30/2004	Jeremy Marshall	3003-1147	5095
466 7590 01/03/2007 YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/500,567

Applicant(s)

MARSHALL ET AL.

Examiner

Melissa A. McCorkle

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 06/30/2004 & 04/11/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 6 is objected to because of the following informalities: there is no antecedent basis for "the cam" in claim 1. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. Claims 1, 5 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, the terms "lost motion connection" and "rotationally fast with the knob" are not described in the specification or the drawings.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirchhofer et al (6,086,567.) Kirchhofer discloses a dose application counter for an injection device with a dose setting element, the counter having a member with a lost motion connection to the dose setting element, whereby movement of said element by and beyond a predetermined amount causes movement of said member to a set extent, each such movement of said member resulting in the indication of usage of the injection device;

Art Unit: 3763

5. the counter comprising a rotatable ring with an annular array of projections co-axial with the knob, the minimum dose requiring the knob to be turned from a zero position through an angle at least as great as the angular spacing of adjacent projections, an element rotatable with the knob and spring-urged to engage a projection when the knob is at zero, and a cam fixed to the body of the device and arranged to disengage said element from the ring when the projection has been pushed round by the element through a predetermined angle and to maintain that disengagement on further rotation, the ring and body having external markings to indicate the circumferential advances of the ring, wherein the application of a dose and the consequent reversion of the knob to its zero position brings said element back to engage another projection while the ring remains static, wherein the ring is positioned between the knob and the body of the device; or wherein the projections are formed by ratchet teeth internal of the ring, and the element that engages the teeth is a peg that extends in the axial direction beyond the ring for cooperation also with the cam; wherein the peg is at the free end of a generally spiral finger whose other end is rotationally fast with the knob, the finger being of plastics material and being so shaped and dimensioned that it acts as a spring;
6. or wherein the cam is in the form of another co-axial ring, but with its circular aperture expanded outwards over a sector corresponding to the pitch between adjacent teeth, the radius of most of the aperture being less than that of the circle tangential to the tips of the teeth;

Art Unit: 3763

7. the counter comprising a unidirectionally rotatable sleeve with multi-start internal screw threading carried by the housing, a projection resiliently carried by the housing, a projection resiliently carried by the plunger, which passes through the sleeve and which, through its projection and the screw threading, generates rotation of the sleeve as it is retracted, the minimum dose requiring the projection to traverse at least the full axial length of the sleeve and the screw threading being shaped so that the resilient projection jumps threads on forward movement of the plunger, with the sleeve held against counter-rotation, and external markings on the sleeve and housing to indicate the circumferential advances of the sleeve, or wherein the unidirectional rotation is achieved by having a ratchet engagement between the sleeve and the housing, or wherein the screw threading comprises coarse pitch square section grooves and the length of the sleeve is such that the rear end of each part-helical groove registers in the axial direction with the forward end of the adjacent groove; or wherein the sides of the grooves that face circumferentially and slightly rearwardly are chamfered at their rear ends so that, as the plunger moves forward, the projection inwards onto the land area between adjacent grooves, so that the projection will then snap into the adjacent groove.

8. Kirchhofer et al discloses the device as stated above, wherein the projections are formed by ratchet teeth internal of the ring, and the element that engages the teeth is a peg that extends in the axial direction beyond the ring for cooperation also with the cam; wherein the peg is at the free end of a generally

Art Unit: 3763

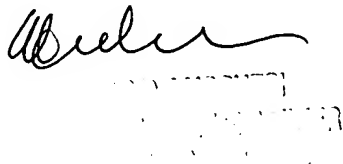
spiral finger whose other end is rotationally fast with the knob, the being being of a plastics material and being so shaped and dimensioned that it acts as a spring.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Melissa A McCorkle  
Examiner